PTO/SB/08a (06-03)

Approved for use through 4/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE ander the Paper of the Paper

C . L	Substitute for form 1449A/PTO			Complete if Known	7	
Substitute for form 1443A/P1O		Application Number	10/790,488	1		
INF	INFORMATION DISCLOSURE			Filing Date	March 1, 2004	1
STA	STATEMENT BY APPLICANT		First Named Inventor	Sherman		
				Group Art Unit	1614	
(Use as many sheets as necessary)		Examiner Name	Delacroix-Muirhead, Cybille TIMOTHY	BETTO		
Sheet	1	of	1	Attorney Docket Number	AM-101314USA	

			U.S. PATENT	DOCUMENTS	
Examiner	C'1- N- 1	Document Number	Publication	Name of Patentee or Applicant of	Pages, Columns, Lines, Where
Initials*	Cite No.1	Number-Kind Code <sup>2(if known)</sup>	Date MM-DD-YYYY	Cited Document	Relevant Passages or Relevant Figures Appear
748	US30	2003/008923-A1	01-09-2003	Dukart, et al.	
. ,					
	ļ				
	ļ				
			<u> </u>		
			1		
	ļ		<del> </del> -		
ı			1	İ	

FOREIGN PATENT DOCUMENTS									
Initials*	Cite	Foreign Patent Document	Publication Date	Name of Patentee or Applicant	Pages, Columns, Lines, Where	T			
	No.1	Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (If known)	MM-DD-YYYY	of Cited Document	Relevant Passages or Relevant Figures Appear	Т <sup>6</sup>			
723	F5	WO 02/098416	12-12-2002	Wyeth Corp.					
KB	F6	WO 02/080975	10-17-2002	Wyeth Corp.		1			
143	F7	WO 02/40000	05-23-2002	Wyeth Corp.					
753	F8	WO 03/020266	03-13-2003	Wyeth Corp.					

Examiner Signature	 Timoth	7 <b>T</b> .	Betton	Date Considered	7	/20	10	7
	 7	)	• .		-77			

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (08-03)

Approved for use through 7/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

						Complete if Known
Substitute	e for form	1449A/P	го		Application Number	10/790,488
INF	INFORMATION DISCLOSURE				Filing Date	March 1, 2004
STA	STATEMENT BY APPLICANT			APPLICANT	First Named Inventor	Sherman
	(Use as many sheets as necessary)		Group Art Unit	unassigned 1614		
(			Examiner Name -	unassigned TIMOTHY BETTON		
Sheet	1	of		6	Attorney Docket Number	AM-101314USA

		······································	U.S. PATENT	DOCUMENTS	
Examiner	Cite No.1	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant Passages or Relevant
Initials*	Cite iii.	Number-Kind Code <sup>2(if known)</sup>	MM-DD-YYYY	Cited Document	Figures Appear
753	US1	3,929,992	12-30-1975	Surendra N. Sehgal, et al.	
158	US2	3,993,749	11-23-1976	Surendra N. Sehgal, et al.	
569	US3	4,401,653	08-30-1983	Chee P. Eng	
TSB	US4	4,885,171	12-05-1989	Surendra N. Sehgal, et al.	
153	US5	5,078,999	01-07-1992	Linda M. Warner, et al.	
Rts	US6	5,080,899	01-14-1992	Robert J. Sturm, et al.	
783	US7	5,100,899	03-31-1992	R. Calne, et al.	
7473	US8	5,206,018	04-27-1993	Surendra N. Sehgal, et al.	
龙龙	US9	5,286,730	02-15-1994	Craig E. Caufield, et al.	
128	US10	5,286,731	02-15-1994	Craig E. Caufield, et al.	
1513	US11	5,288,711	02-22-1994	Robert D. Mitchell, et al.	
TEB	US12	5,321,009	06-14-1994	William L. Baeder, et al.	
740	US13	5,362,718	11-08-1994	Jerauld S. Skotnicki, et al.	
TLO	US14	5,387,589	02-07-1995	Prasad S. Kulkarni	·

	FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or Applicant	Pages, Columns, Lines, Where Relevant Passages or	Т°			
Initials*	No.1	Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (If known)	MM-DD-YYYY	of Cited Document	Relevant Figures Appear				
148	Fl	EP - 0 525 960 - A1	02-03-1993	Glenn A. Miller, et al.					
163	F2	WO02/066019 - A2	08-29-2002	Novartis AG					
123	F3	WO99/52514 - A	10-21-1999	Eli Lilly and Company		Х			
Pd3	F4	WO02/13802 - A2	02-21-2002	American Home Product					

-						
Examiner Signature	100	Date	1	100	100	
		Considered		1 4	7º	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. There Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 7/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

					Complete if Known
Substitute	Substitute for form 1449A/PTO		Application Number	10/790,488	
INF	<b>INFORMATION DISCLOSURE</b>			Filing Date	March 1, 2004
STA	STATEMENT BY APPLICANT		First Named Inventor	Sherman	
				Group Art Unit	unassigned 1614
(	(Use as many sheets as necessary)		Examiner Name	unassigned TIMOTHY BETTON	
Sheet	2	of	6	Attorney Docket Number	AM-101314USA

			U.S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
7/h	77015	Number-Kind Code <sup>2(if known)</sup>		Jay J. Armstrong	7.92.03.447.03
123	US15	5,496,832	03-05-1996	<del></del>	
76%	US16	5,516,781	05-14-1996	Randall E. Morris	
158	US17	5,561,138	10-01-1996	Jay J. Armstrong	
150	US18	2002/0091137-A1	07-11-2002	Dukart, et al.	
Ra	US19	5,066,493	11-19-1991	S.N. Sehgal, et al.	
-RB	US20	2002/0183239-A1	12-05-2002	Gibbons, et al.	
1213	US21	2002/0183240-A1	12-05-2002	Gibbons, et al.	
168	US22	2003/0050222-A1	03-13-2003	Rabindran, et al.	
121	US23	6,002,008	12-14-1999	Wissner, et al.	
152	US24	6,277,983	08-21-2001	Shaw, et al.	
750	US25	6,617,333-B2	09-09-2003	Rabindran, et al.	
750	US26	2002/0198137-A1	12-26-2002	Dukart, et al.	
F8	US27	5,728,710	03-17-1998	Luengo, Juan	
BB.	US28	2003/0153593-A1	08-14-2003	Dukart et al.	
15/2	US29	60/552,122	03-11-2004	Bayever et al.	

		FOREIGN I	PATENT DOCUMENTS			
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	76
						_
						_
	,			1		1

Examiner Signature	Camaidamad //	23/07	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. The reference of the reign of the Emperor must precede the serial number of the patent document. Akind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Iranslation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

	<u> </u>				Complete if Known
Substitut	Substitute for form 1449B/PTO			Application Number	10/790,488
INF	ORMA	TION	DISCLOSURE	Filing Date	March 1, 2004
STA	STATEMENT BY APPLICANT			First Named Inventor	Sherman
				Group Art Unit	unassigned \614
	(Use as many sheets as necessary)			Examiner Name -	unassigned TIMOTHY BETTON
Sheet	3	of	6	Attorney Docket Number	AM-101314USA

<del></del>		NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
KB	L1	S.N. SEHGAL, et al., Rapamycin (AY-22,989), A New Antifungal Antibiotic, II. Fermentation, Isolation and Characterization, J. Antibiot., October 1975, 727-732, 28	
TEB	L2	C.V. VEZINA, et al., Rapamycin (AY-22,989), A New Antifungal Antibiotic, I. Taxonomy of the Producing Streptomycete and Isolation of the Active Principle, J. Antibiot., October 1975, 721-726, 28	
128	L3	H.A. BAKER, et al., Rapamycin (AY-22,989), A New Antifungal Antibiotic, III. In Vitro and In Vivo Evaluation, J. Antibiot., June 1978, 539-545, 31(6)	
1/2B	L4	M.J. STARUCH, et al., FK506 and Rapamycin Inhibit Murine T Cell Activation Through Different Mechanisms. FASEB, 1989, 3411, 3	<u> </u>
	L5	F.J. DUMONT, et al., Rapamycin Blocks the Immunosuppressive Effect of FK506 But Not That of Cyclosporin A. FASEB, 1989, 5256, 3	
168 168	L6	R.Y. CALNE, et al., Prolonged Survival of Pig Orthotopic Heart Grafts Treated with Cyclosporin A, The Lancet, June 3, 1978, 1183-1185	
148	L7	R. MARTEL, et al., Inhibition of the immune response by rapamycin, a new antifungal antibiotic, Can. J. Physiol. Pharmacol., February 1977, 48-51, 55	
160	L8	J. ALEXANDRE, et al., Rapamycin and CCI-779, Bull. Cancer, October 1999, pages 808-811, 86(10) (Only abstract of attached article has English translation)	
EB.	L9	A. PERREN, et al., Immunohistochemical Evidence of Loss of PTEN Expression in Primary Ductal Adenocarcinomas of the Breast, Am. J. Pathology, October 1999, pages 1253-1260, 155, No. 4	
150	L10	J.E. DANCEY, et al., Rapamycin-Sensitive Signal-Transduction Pathways: Protein Translation Control of Cell Proliferation, ASCO Educational Book, Spring 2000, pages 68-75	
	L11	M. HIDALGO, et al., The rapamycin-sensitive signal transduction pathway as a target for cancer therapy, Oncogene, December 27, 2000, 6680-6686, 19	_
1/20 1/4B	L12	E.A. SAUSVILE, et al., New Agents-Noncytotoxins, Antiangiogenesis, ASCO Educational Book, Fall 1998, pages 112-117	
143	L13	T. SCHMELZLE, et al., TOR, a Central Controller of Cell Growth, Cell, October 13, 2000, pages 253-262, 103	
FeB	L14	J. ALEXANDRE, et al., "CCI-779, a new rapamycin analog, has antitumor activity at doses inducing only mild cutaneous effects and mucositis; early results of an ongoing phase 1 study", Proceedings of the 10th NCI/EORTC/AACR Symposium, 1999 (poster presentation)	

	<b></b>			<u> </u>
Examiner Signature	1/14	Date Considered	1221	07
	<del> ,                                    </del>			

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 7/31/2006. OMB 0551-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

-					Complete if Known
Substitute for form 1449B/PTO				Application Number	10/790,488
INFORMATION DISCLOSURE				Filing Date	March 1, 2004
STA	STATEMENT BY APPLICANT			First Named Inventor	Sherman
				Group Art Unit	unassigned 1614
	(Use as many sheets as necessary)			Examiner Name	unassigned TIMOTHY BETTON
Sheet	4	of	6	Attorney Docket Number	AM-101314USA

	<del></del>	NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
743	L15	J.J. GIBBONS, et al., The effect of CCI-779, a novel macrolide anti-tumor agent, on the growth of human tumor cells in vitro and in nude mouse xenografts in vivo, Proceedings of the American Association for Cancer Research, March 1999, 301, #2000, v.40	
448	L16	B. GEOERGER, et al., Rapamycin analog CCI-779 inhibits growth of human medulloblastoma xenografts, Proceedings of the American Association for Cancer Research, March 1999, 603, #3978, v.40	
448	L17	B. GEOERGER, et al., Cytotoxic effects of rapamycin in human medulloblastoma cell lines and xenografts: as single agent or in combination chemotherapy, Proceedings of the American Association for Cancer Research, 1999, #296	
842	L18	J. ALEXANDRE, et al., Phase I Study of CCI-779, Novel Rapamycin Analog: Preliminary Results, Proceedings of the American Association for Cancer Research, March 2000, 613, #3897, v.41	
FES.	L19	M. HIDALGO, et al., Phase I and pharmacological study of CCI-779, a cell cycle inhibitor, Proceedings of the 11th NCI/EORTC/AACR Symposium, November 2000, 4548s, 6 (Supp.), #413	
128	L20	M. HIDALGO, et al., A phase I and pharmacological study of CCI-779, a rapamycin ester cell cycle inhibitor. Annals of Oncology, October 2000, 133, 11(4)	
FR	L21	E. RAYMOND, et al., CCI-779, an ester analogue of rapamycin that interacts with PTEN/PI3 kinase pathways: A phase I study utilizing a weekly intravenous schedule, Proceedings of the 11th NCI/FORTC/AACR Symposium, November 2000, Abstract 414	
PR	L22	E. RAYMOND, et al., CCI-779, a Rapamycin Analog and Multifaceted Inhibitor of Signal Transduction: a Phase I Study, Proceedings of ASCO, 2000, 187a, 19, #726	
F20	L23	E. RAYMOND, et al., CCI-779, a Rapamycin Analog with Antitumor Activity: A Phase I Study Utilizing a Weekly Schedule, Proceedings of ASCO, 2000, 187a, 19, #728	
1253	L24	M. HIDALGO, Phase 1 and Pharmacological Studies with the Rapamycin Analog CCI-779  Administered as a 30 Minute Infusion, NCI-CTEP Drug Development Meeting, October 1999	
EB	L25	M. ABOU-GHARBIA, Medicinal Chemistry Approaches for Optimization of Early Leads in Drug Candidates: The Discovery of Calicheamicin, Rapamycin and EAA-090, International Conference on Pure and Applied Heterocyclic Chemistry, March 2000	
FB	L26	R. LANGRETH, et al., Drug Progress on Hard-to-Treat Cancers Is Cited, The Wall Street Journal, November 17, 1999, vol. 234	

E-aminar Signature	Date	1/20/	
Examiner Signature	Considered	1/22/0	//
	Considered		<del></del>

<sup>•</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

'Applicant's unique citation designation number (optional). 'Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

		-			Complete if Known
Substitute for form 1449B/PTO				Application Number	10/790,488
INFORMATION DISCLOSURE				Filing Date	March 1, 2004
STATEMENT BY APPLICANT		First Named Inventor	Sherman		
				Group Art Unit	unassigned 1614
(Use as many sheets as necessary)			as necessary)	Examiner Name	-unassigned_ TIMOTHY BETTON
Sheet	5	of	6	Attorney Docket Number	AM-101314USA

<u> </u>		NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
148	L27	B. GEOERGER, et al., Antitumor Activity of the Rapamycin Analog CCI-779 in Human Primitive Neuroectodermal Tumor/Medulloblastoma Models as Single Agent and in Combination Chemotherapy, Cancer Research, Vol. 4, No. 61, February 15, 2001, pages 1527-1532, XP-001079526	
1/20	L28	J. BONI, et al., Pharmacokinetics of escalating doses of CCI-779 in combination with 5-fluorouracil and leucovorin in patients with advanced solid tumors, European Journal of Cancer, Vol. 37, NR. Suppl. 6, page S68, XP001084492, October 2001	
KB	L29	GUPTA, R.A., et al., Combinations for Cancer Prevention, Nature Medicine, Vol. 6, No. 9, XP-002223840. September 2000	
428	L30	TORRANCE, et al., Combinatorial Chemoprevention of Intestinal Neoplasia, Nature Medicine, Vol. 6, No. 8, XP-002223841, September 2000	
-158	L31	ALBERTS, et al., New Perspectives on an Old Friend: Optimizing Carboplatin for the Treatment of Solid Tumors, The Oncologist, Vol. 3, No. 1, pages 15-34, February 1998	
Fig.	L32	SCHWARTSMANN, Marine Organisms and Other Novel Natural Sources of New Cancer Drugs, Annals of Oncology, Vol. 11, No. 3, pages 23-243, XP-001070989, October 13, 2000	
F5B	L33	PUNT, et al., A phase 1 Study of Escalating Doses of CCI-779 in Combination with 5-fluorouracil and Leucovorin in Patients with Advanced Solid Tumors, European Journal of Cancer, Vol. 37, No. Supplement 6. Page S17, October 2001	
16B	L34	CLACKSON, et al., Broad Anti-Tumor Activity of ap23573, an mTOR Inhibitor in Clinical Development, Proc. Am. Soc. Clin. Oncol. 22, page 220, abstract 882, 2003	ļ
FB	L35	BASELGA, et al., CCI-779 study 204: Phase II, 3-arm study of CCI-779 in combination with letrozole in postmenopausal women with locally advanced or metastatic breast cancer: preliminary results. December 19, 2003 (abstract presented to ASCO for presentation in June 2004)	
128	L36	Y. SHI, et al., Rapamycin Enhances Apoptosis and Increases Sensitivity to Cisplatin in Vitro, Cancer Research, Vol. 55, 9, May 1, 1995, pages 1982-1988, XP-002040888	<u> </u>
KB	L37	GREENBERGER, et al., A New Irreversible Inhibitor of Epidermal Growth Factor Receptor Tyrosine Kinase for the Treatment of Cancer, Clinical Cancer Research, Vol. 6, page 38, November 2000, XP-001120789	ļ ·
KO	L38	CARTER, et al., Chemotherapy of Cancer, Second Edition, John Wiley & Sons, NY, NY, pages 362-365, 1981	

	_					
	76	Date	_	7	<i></i>	. 1
Examiner Signature		Date	- / /	つクイ	0	, ,
1 1		Considered	/_/	12	, •	/
			<del> / /</del>			
	7/		ι,	•	,	

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation in lot in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USFTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (08-03)

Approved for use through 7/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<u> </u>					Complete if Known
Substitute	e for form	1449B/PTO		Application Number	10/790,488
INF	ORMA	TION	DISCLOSURE	Filing Date	March 1, 2004
STA	STATEMENT BY APPLICANT			First Named Inventor	Sherman
				Group Art Unit	unassigned \614
ļ	(Use as ma	any sheets a	s necessary)	Examiner Name	-unassigned TIMOTHY BETTON
Sheet	6	of	6	Attorney Docket Number	AM-101314USA

		NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
12	L39	ENG, et al., Activity of Rapamycin (AY-22,989) Against Translated Tumors, The Journal of Antibiotics, Vol. 37, No. 10, pages 1231-1237, XP001098253, October 1984	
148	L40	TSAI, et al., Combination cytotoxic effects of cis-diamminedichloroplatinum(II) and 5-fluorouracil with and without leucovorin against human non-small cell lung cancer cell lines, Cancer Res., 53 (5), pages 1079-1084, March 1, 1993	
		·	ļ. 
		<u> </u>	

Examiner Signature	74	Date Considered	7)	22	8	
·			T			

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.